

COLCRYS® (colchicine, USP) tablets

Introduction

Public Law 102-585, also known as the Veteran's Healthcare Act ("the Act"), was established in 1992, and promulgated January 1, 1993. The statute requires all manufacturers of "covered drugs" to enter into a Master Agreement (MA) and Pharmaceutical Pricing Agreement (PPA) for each covered drug and make them available for procurement on the Federal Supply Schedule (FSS). A covered drug is defined by the statute as any legend drug that is Food and Drug Administration (FDA) approved under a New Drug Application (NDA) or Biological Licensing Agreement (BLA). The Act mandates a 24% statutory discount for pricing establishment to the Big 4 agencies called the Federal Ceiling Price (FCP). The General Services Administration (GSA) oversees the FSS contract schedules and delegated the authority to the Department of Veterans Affairs (VA). GSA policy does not allow FSS items that are manufactured in non-designated countries (Trade Agreements Act), which conflicts with the MA and PPA and the Federal Acquisition Regulation (FAR).

Background/Justification

- Only source of medically necessary item
 - Covered drugs are single source legend drugs that are FDA approved under a NDA or BLA
 - Generic alternatives may not be available due to drug shortages, backorders or medical need (i.e., low therapeutic index)
 - When generic alternatives are available, there will still be a need for the single source product due to:
 - allergies to dyes or other inactive ingredients in a generic(s), which can differ between manufacturers
 - clinical failure on a generic(s), where brand has worked
 - Adverse Drug Events (ADE) on a generic(s), where brand has not cause ADEs
 - clinical judgment of provider not to switch brand to generic(s), due to fragile disease state
 - the fact that brand and generic are considered bioequivalent by FDA based on a range and may not have exactly the same response in every patient
- Direct purchases are not an option
 - Next day delivery of pharmaceuticals is mission critical to VHA pharmacy to ensure Veterans receive the drugs prescribed by their physicians without a lapse in care. A lapse in drug supply will negatively impact patient safety. When covered drugs are not included on FSS contracts, it creates a barrier to ordering drugs and negatively impacts patient care
 - Vendor may make the decision to not sell direct to customers
 - Pharmacy Ordering Officers (OO) must create an account with the vendor and use the government purchase card ($\leq \$3000$), which can create a delay of several days
 - For orders $> \$3000$, purchases must be referred to a warranted contracting officer, which can create a delay of several days to several weeks
 - In any case, there is no mechanism for the government to purchase the covered drug at the statutory FCP; open market prices are charged
 - Even if the facilities could efficiently make a direct purchase, they could not verify the accuracy of FCP pricing, since FCPs are confidential

- Manufacturers are prohibited from submitting any pricing to the pharmaceutical prime vendor (PPV) for government customers per the PPV contract
- Clinical Indications / FDA approved indications
 - Approved: Jul 29, 2009 (NDA 022352)
 - COLCRYS® (colchicine, USP) tablets are indicated for:
 - Prophylaxis and Treatment of Gout Flares in adults
 - Familial Mediterranean fever (FMF) in adults and children 4 years or older
- Annual Estimates

Annual Purchases					
ndc	Description	Bottle Size	# of Bottles	Total Cost	Agency
64764011907	COLCHICINE 0.6MG TAB	30	104881	\$10,437,773	VA
64764011901	COLCHICINE 0.6MG TAB	100	35674	\$11,708,653	VA
64764011907	COLCHICINE 0.6MG TAB	30	2477	\$247,160	IHS
64764011901	COLCHICINE 0.6MG TAB	100	1360	\$451,254	IHS
64764011907	COLCHICINE 0.6MG TAB	30	98	\$11,458	BOP
64764011901	COLCHICINE 0.6MG TAB	100	288	\$101,491	BOP
64764011907	COLCHICINE 0.6MG TAB	30	0	\$0	DOD*
64764011901	COLCHICINE 0.6MG TAB	100	0	\$0	DOD*
*Pending Data from DoD					